VALVULAR DISEASE: AORTIC

TCT-610 Incidence, Predictive Factors and Impact of Delirium after Transcatheter Aortic Valve Implantation
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BACKGROUND To investigate the incidence, predictive factors and impact of postoperative delirium (POD) among patients treated by transcatheter aortic valve implantation.

METHODS A retrospective observational cohort study of 268 consecutive patients who underwent TAVI at our institute was conducted. Delirium was diagnosed according to the Diagnostic and Statistical Manual of Mental Disorder, 4rd Edition criteria. Primary outcome of this study was the presence of inhospital POD after TAVI.

RESULTS The incidence of POD after TAVI was 13.4% (n=36). Of these cases, 18 were associated with post-procedural complications, including major vascular complications/bleeding (n=4), stroke (n=3), acute kidney injury (n=3), atrial fibrillation (n=4) and infectious disease (n=4). POD was most frequently diagnosed on the second day after TAVI (IQR: 1-5) and was associated with prolonged in-hospital stay regardless of complications (in uncomplicated TAVI: 6(3-10) vs. 5(4-5) days, P<0.001; and in complicated TAVI: 9.8(8-15) vs. 6.5(5-9) days, P<0.001). Predictors of POD were non- transmural (transapical/transaortic) access (Odds Radio (OR) 7.53; 95% confidence interval [CI] 3.19-17.73), current smoking (OR 3.84; 95% CI 2.12 to 12.14), symptomatic carotid stenosis (OR 3.05; 95% CI 1.10 to 8.50), atrial fibrillation (OR 2.61; 95% CI 1.37 to 6.02) and age (OR 1.09; 95% CI 1.00 to 1.18). After a median follow-up of 16 [6-27] months, patients who developed POD showed higher mortality (36% vs. 16%; P<0.001). POD remained a significant independent predictor of mortality when adjusted for age, sex and occurrence of complications (Hazard Ratio (HR): 1.34; 95% CI 1.17 to 4.57).

CONCLUSIONS POD after TAVI has an incidence of 13% and occurs early in the postoperative course. Non-transmural access is strongly associated with the occurrence of POD. Patients who develop POD show prolonged in-hospital stay and impaired long term survival.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Post-operative complication, Transcatheter aortic valve implantation

TCT-611 Differences in frame geometry between balloon-expandable and self-expanding trans-catheter heart valves and its relation with aortic regurgitation
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BACKGROUND Patient- and procedure related factors are known to be associated with aortic regurgitation (AR) after Transcatheter Aortic Valve Replacement (TAVR). Yet, AR may also be caused by a specific device-host interaction. We sought to elucidate the role of frame geometry in the occurrence of aortic regurgitation after Medtronic Corevalve (MCS) and Edwards-SAPIEN valve (ESV) implantation.

METHODS One-hundred-and-fifty consecutive patients who underwent TAVR with the MCS or ESV in whom rotational angiography was performed of whom 16 patients were excluded from analysis because of poor image quality; total study population 134 (MCS 84, ESV 50). Frame analysis was performed at 3 predefined levels: MCS; inflow, nadir of the leaflets and central coaptation, ESV; inflow, mid segment and outflow. The degree of frame expansion was calculated by the measured perimeter divided by nominal frame perimeter at the inflow. The eccentricity at the nadir of the MCS frame and mid segment of the ESV was adjusted to the eccentricity of the native valve using the following equation: (Eccentricity nadir or mid segment – Eccentricity native annulus / Eccentricity native annulus) x 100. AR immediately post TAVI and at discharge was assessed using contrast angiography (Sellers) and Doppler echocardiography (VARC2). Distinction was made between patients with non and mild and those with moderate and severe AR.

RESULTS Patients treated with the MCS valve underwent more often balloon pre-dilation than patients treated with the ESV valve (95.2% vs 82.0%, p=0.012) and the size of the valve related to aortic annulus was larger in MCS treated patients for all MSCT-derived annuli. The degree of expansion of the MCS valve was less at its inflow in comparison to the ESV (83 ± 7 vs 92 ± 4, p < 0.001), but higher at its nadir and outflow. Yet, the MCS frame was more in flow in the ESV at all levels (Inflow: 82 ± 8 vs 95 ± 3, p < 0.001; nadir/mid segment: 83 ± 8 vs 95 ± 4, p < 0.001; coaptation/oufow: 90 ± 6 vs 96. ± 3, p < 0.001). This was also the case for the adjusted eccentricity (MCS 4 ± 13 vs ESV 21 ± 11, p < 0.001) which was more prevalent in the MCS than ESV treated (MCS 36% vs 2% p < 0.001). The rate of more-than-mild AR was 23.6% in the MCS vs. 13.6% in the ESV (p=0.161). The absolute and adjusted eccentricity at the nadir/mid segments and at the coaptation/outflow were associated with significant AR by echocardiography. This also holds for the presence of a frame more elliptical than the native annulus (AR ≥ moderate 48 vs. 17 %, p = 0.002).

CONCLUSIONS Despite more oversizing, the inflow of the MCS frame is less expanded than the ESV. Also, the MCS is more elliptical at all the levels. Eccentricity was associated with more-than-mild AR. These data indicate that intrinsic device related properties contribute to AR post TAVI. “Disclaimer: The concepts and information presented in this paper are based on research and are not commercially available.”

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Rotational angiography, Transcatheter aortic valve replacement

TCT-612 Determinants of image quality of rotational angiography with motion compensation for on-line frame analysis of trans-catheter heart valves
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BACKGROUND There is an increasing clinical experience with various catheter-based valve technologies with different interaction with the recipient. This has lead to an interest in on-line assessment of frame geometry to better understand and/or to improve the immediate result. The only technique that allows that assessment is rotational angiography (R-angio). We sought to evaluate the determinants of image quality of rotational angiography for on-line frame analysis after Trans-catheter Aortic Valve replacement (TAVR).

METHODS A total of 179 patients underwent R-angio with motion compensation after TAVR using 4 valves (Medtronic Corevalve (MCS, n=98), Edwards-SAPIEN (ESV, n=52), Boston Sdara Lotus (BSL, n=23), Sapiens Medical Portico (SPV, n=26). We defined immediately acquiring 133 images in 5 seconds along a 198° arc during breath hold. From the projection data a motion compensated 3D image was reconstructed with research prototype software (Siemens AG, Healthcare, Forchheim, Germany). Image quality was evaluated using the following score: grade 1; excellent image quality, grade 2; distinction between struts and artifacts possible, grade 3; some regions distinction between struts and artifacts cannot be made, grade 4; degraded, grade 5; strongly degraded. Distinction was made between patients with good image quality (1, 2) and with insufficient or poor image quality (3-5). Multivariable logistic regression was used to study the independent predictors of image quality.

RESULTS Grade 1 & 2 image quality was achieved in 128 patients (72%). By univariable analysis only valve type (BSL) and the presence of an artefact (permanent pacemaker, TOE probe, pigtail, stitches, pulmonary or other radiopaque objects) negatively affected image quality. For valve type, the prevalence of good image quality - in descending order of frequency - was: ESV (45/52, 86%), SPV (5/6, 83%), MCS (68/98, 69%) and BSL (10/23, 48%). Image quality was good in 79% of the patients when no artefact was present vs 63% in the presence of an artefact. Arrhythmia (e.g. atrial fibrillation, premature ventricular contractions) was present in 35/179 patients (20%) but did not affect image quality (good image quality in 29/35, 83%). By multivariate analysis (which BMI was forced - BMI of patients with good and poor image quality: 26.5 ± 27.5, respectively), the
following variables were identified as predictors of poor image quality in descending order of frequency: BSH valve (Odds 3.5 IC 95% [1.3 - 9.6], p = 0.02), presence of an artifact (Odds 2.5 IC 95% [1.2 - 5.4], p = 0.02) and BMI (Odds 1.1 IC 95% [1.0 - 1.2], p = 0.04).

CONCLUSIONS
R-angiography with dedicated motion compensation software offers good image quality for on-line frame analysis in 72% of the patients. Image quality predominantly depends on valve type, presence of artifacts and patient-related variables such as BMI. *Disclaimer: The concepts and information presented in this paper are based on research and are not commercially available.*

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS
Rotational angiography, Transcatheter aortic valve replacement

TCT-615
Extracranial Carotid And Vertebral Artery Disease And The Risk Of Stroke Following Trans-catheter Aortic Valve Replacement

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BACKGROUND
Stroke is a feared complication of trans-catheter aortic valve replacement (TAVR). Carotid and vertebral artery duplex ultrasonography is routinely obtained prior to TAVR, but the significance of extracranial carotid and vertebral artery disease (CVD) on the risk of stroke following TAVR is unknown. The purpose of this study is to assess the impact of CVD on the risk of stroke following TAVR.

METHODS
We reviewed 294 consecutive cases of TAVR at a single tertiary referral academic medical center from June, 2008 to March, 2015. We included 263 patients who underwent routine carotid and vertebral artery duplex ultrasonography prior to TAVR in a retrospective cohort study. Patients with at least 50% stenosis of a carotid or vertebral artery were identified as having CVD, and patients were stratified into 2 groups by the presence or absence of CVD. The primary outcome was stroke within 30 days of TAVR. We adjudicated stroke by the guideline recommendations of the Valve Academic Research Consortium. Secondary outcomes included 30-day mortality and overall survival following TAVR. We used chi2 and Fischer’s exact tests to compare categorical variables and independent samples t tests to compare continuous variables. We used Kaplan Meier life table analysis to assess overall survival. We included univariate predictors of stroke at P < 0.10 in a multivariable logistic regression to identify predictors of stroke after TAVR.

RESULTS
CVD was present in 51 (19%) patients. The CVD group had higher rates of coronary artery disease, prior coronary artery bypass surgery, and peripheral artery disease compared to the non-CVD group. There was no significant difference in the rate of prior stroke or the burden of aortic atheroma by intra-operative trans-esophageal echocardiogram between CVD and non-CVD patients. Trans-femoral access was less common in the CVD group (55% vs. 77%, p < 0.01). Stroke occurred in 18 (6.8%) patients within 30 days after TAVR. No patients with CVD suffered a stroke. There was no difference in 30-day mortality (10% vs 4%, p = 0.11) and overall survival (log-rank test, p = 0.80) between the CVD and non-CVD groups. CVD was not a significant predictor of stroke following TAVR by logistic regression. In a multivariable model, there were no significant independent predictors of stroke after TAVR, but baseline antplatelet therapy showed a trend toward a protective effect, and higher pre-TAVR mean aortic valve gradient showed a trend toward increased risk of stroke (table).

CONCLUSIONS
CVD is not associated with an increased risk of stroke or death following TAVR. The routine screening of CVD prior to TAVR does not appear justified.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS
Carotid stenosis, Stroke, Transcatheter aortic valve replacement

TCT-614
Aortic Root and Anatomical Exclusion for Transcatheter Aortic Valve Implantation

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BACKGROUND
Patients with severe aortic stenosis who are referred for transcatheter aortic valve replacement (TAVR) need to meet aortic root and aortic annular anatomical inclusion criteria. We sought to characterize the number of patients that could not have the currently available transcatheter valves (Sapien XT and CoreValve). We screened 400 patients with severe aortic stenosis who were referred for TAVR between 2010-2014 who had had multi-detector computed tomographic (MDCT) imaging. Annuus measurements of the basal ring (short- and long-axis, area-derivered diameter), coronary ostia height, sinus area (SA), sino-tubular junction area (STJ), calcification and eccentricity index (EI, 1-short axis/long axis) were made.

RESULTS
The vast majority of patients were able to be offered a currently available TAVR valve (88%). We identified 49 patients who were excluded for anatomical annular characteristics alone. Large aortic annuli were the most common reason for anatomical exclusion (704 ± 79 mm2; n = 39, 80%). In addition these large annuli were more elliptical (EI, 1.39 ± 0.11) with more eccentric calcification (68%). The presence of low coronary heights (n = 6 mm: n = 19, 18 %) from the aortic annular plane was the next most common reason. The left main coronary artery was more commonly lower than the right coronary artery and low coronary heights with effaced coronary sinuses appeared occur together (n = 11, 57 %). Small aortic annuli were the least common (290 ± 50 mm2; n = 1, 2 %) cause for exclusion from TAVR therapy. None of the patients who were excluded form TAVR therapy had more than one annular reason for TAVR exclusion.

CONCLUSIONS
Most patients with severe aortic stenosis who are referred for TAVR can be offered a transcatheter valve. However, 12 % of patients cannot be offered a therapy due to anatomical exclusion criteria. This was primarily due to the presence of large aortic annuli and low coronary heights.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS
Aortic stenosis, TAVR

TCT-615
First Report of Three-Year Outcomes With the Repositionable and Fully Retrievable Lotus Aortic Valve Replacement System: Results From The REPRISE I Feasibility Study

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BACKGROUND
The repositionable, fully retrievable, CE-marked Lotus Valve is designed to facilitate controlled, precise positioning and minimize paravalvular aortic regurgitation. Results to 3 years post-implantation with Lotus have not yet been reported.

METHODS
REPRISE I is a prospective, single-arm, 3-center feasibility study designed to assess acute safety and performance of the 23mm Lotus Valve in symptomatic patients with calcific aortic stenosis who were considered high surgical risk by the Heart Team.

RESULTS
The Lotus Valve was implanted in 11 female patients with a mean age 83.0 ± 3.6 years and a mean STS score 4.9 ± 2.5%. Frailty measures included gait speed >66 (9/11), grip strength <18kg (7/11), and cognitive dysfunction (5/11; defined as a score < 4 on the

<table>
<thead>
<tr>
<th>Predictors of Stroke Following TAVR</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior coronary artery bypass surgery</td>
<td>0.33</td>
<td>0.04 to 1.89</td>
<td>0.32</td>
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<tr>
<td>Prior dyslipidemia</td>
<td>0.40</td>
<td>0.31 to 1.38</td>
<td>0.35</td>
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<td>Baseline antiplatelet therapy</td>
<td>0.29</td>
<td>0.08 to 1.02</td>
<td>0.05</td>
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<tr>
<td>Aortic atherosclerotic &gt;2mm thickness</td>
<td>3.71</td>
<td>0.68 to 20.12</td>
<td>0.13</td>
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<tr>
<td>Trans-aortic access</td>
<td>3.41</td>
<td>0.56 to 20.97</td>
<td>0.19</td>
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<tr>
<td>Pre-TAVR mean aortic valve gradient (increasing continuous variable by mm Hg)</td>
<td>1.05</td>
<td>1.00 to 1.11</td>
<td>0.07</td>
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